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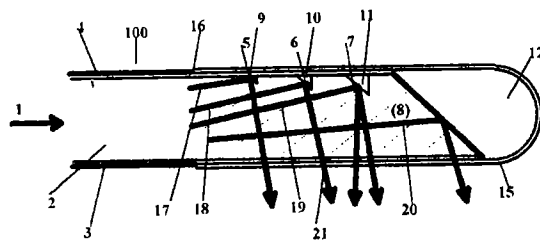
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Q Radial!medical!laser!delivery!device.

Q The! present! invention! involves! a! medical! delivery! system! capable! of! emitting! radiation! with! wavelengths! between! 190! nm! and! 16! μ m! in! one! or! more! essentially! directed,! predetermined! patterns.! It! includes! at! least! one! solid! optical! fiber,! having! a! core! (2)! and! a! cladding! (3)! on! the! core.! The! cladding! has! a! refractive! index! smaller! than! the! core,! having! an! input! end! suitably! configured! to! connect! to! an! appropriate! radiation! source! and! having! a! distal! end! in! the! proximity! of! which! two! or! more! grooves! (5-7)! are! penetrating! into! the! core.! The! grooves! have! at! least! partial! reflector! capability! so! as! to! deflect! radiation! thereto! radially! in! one! or! more! predetermined! patterns. The! invention! also! includes! methods! of! performing! medical! procedures! utilizing! the! afore-said! device.



Fig! 1

BACKGROUND! OF! THE! INVENTION

1. Field! of! the! Invention

This! invention! relates! to! a! laser! delivery! device,! and! more! particularly! to! such! delivery! devices that! emit! radiation! radially! from! the! distal! end! of! an optical! fiber.

2. Prior! Art! Statement

Technological! change! in! laser! delivery! devices is! rapidly! taking! place! in! the! laser! medical! field with! the! onset! of! minimally! invasive! procedures such! as! laser! laparoscopy.! The! laparoscopist,! a physician! or! surgeon! who! performs! laparoscopies, is! often! challenged! with! positioning! the! delivery device,! i.e.,! the! optical! fiber(s),! at! angles! radially! to the! laparoscope! axis! in! order! to! irradiate! the! target perpendicularly.! However,! in! many! cases! moving! a laparoscope! radially! is! very! difficult! or! is! impossible. As! an! alternative,! the! laparoscope,! which! is normally! rigid,! may! have! an! adjustable! fiber! deflector! called! a! bridge.! The! bridge! may! be! adjusted! at the! proximal! end! causing! radial! movements! to! the distal! end! of! the! fibers.! This! adjustment! is,! however,! limited! by! the! bend! radius! of! the! fibers! and/or the! bridge! device! and! cannot! offer! full! capabilities. Therefore,! techniques! to! emit! radiation! radially from! the! distal! end! of! the! fiber! without! bending! are needed.

Reflecting! tips! secured! on! the! distal! fiber! end, such! as! metal! caps! incorporating! a! mirror! surface at! a! 45! °! angle! relative! to! the! fiber! axis! are! state! of the! art! and! have! been! used! successfully! in! procedures! such! as! lithotripsy! with! high! pulse! powered (Q-switched)! Yttrium! Aluminium! Garnet! Lasers.

For! many! surgical! procedures! requiring! an even! illumination! (such! as! prostate! treatment! or photodynamic! therapy)! the! point! source-like! radiation! pattern! from! this! known! device! is! ill! suited.

The! state! of! the! art! devices! used! in photodynamic! therapy! incorporate! a! glue,! i.e.,! epoxy,! containing! cap! with! scattering! medium! dispersed! in! it.! These! caps! can! produce! a! relatively homogeneous! radial! pattern.! However,! the! output! is diffuse! and! they! are! somewhat! limited! in! power handling! capability! due! to! the! limitations! of! the glue.

In! summary,! the! present! state! of! the! art! for radial! laser! radiation! delivery! is! restricted! to! either point! sources! (size! of! the! source! comparable! to! the fiber! cross! section)! or! to! essentially! diffuse! radiators! with! limited! power! handling! capabilities.! United States! Patent! No.! 4,740,047! describes! a! point source! type! of! device! using! a! cut! fiber! with! a reflective! surface! to! deflect! a! beam! for! lateral! application.

While! methods! to! control! the! fiber! tip! temperature! aimed! at! preventing! damage! to! the! distal! tip! of the! laser! delivery! device! have! been! described! in United States! Patent! No.! 5,057,099! no! control method! has! been! described! to! prevent! or! limit damage! to! the! tissue! itself! that! seems! applicable! to treatments! such! as! laser! prostatectomy.! Thus, while! this! recently! issued! patent! allows! for! temperature! control! to! optimize! particular! surgical! or medical! procedures,! it! does! not! address! or! satisfactorily! resolve! the! need! for! proper! lateral! and radial! delivery! of! laser! beams! to! satisfy! varied needs! for! varied! procedures.

Thus,! the! prior! art! neither! teaches! nor! renders obvious! the! present! invention! device! set! forth! herein.

SUMMARY! OF! THE! INVENTION

Described! is! a! device! capable! of! delivering high! laser! power! at! selected! angles! or! any! angle essentially! radially! to! the! axis! of! an! optical! fiber. The! fiber! emits! the! laser! radiation! from! a! wider area! at! the! distal! end! in! a! well! directed,! essentially non-diffuse! pattern! with! a! plurality! of! reflective! surfaces,! having! different! angles! or! sizes,! within! the fiber! itself.

Surgical! procedures,! such! as! transurethral! laser! prostatectomy,! are! beneficially! performed! using preferred! embodiments! of! the! device.! The! device may! comprise! feedback! control! mechanisms! from the! tissue! to! regulate! radiation! delivery! dosimetry with! procedural! requirements.

BRIEF! DESCRIPTION! OF! THE! DRAWINGS

The! invention,! together! with! further! objects, advantages,! aspects! and! features! thereof,! will! be more! clearly! understood! from! the! following! description! taken! in! connection! with! the! accompanying drawings:

Figure! 1! is! a! side! view! of! a! radial! medical radiation! delivery! device! using! air! pockets! created! by! the! core! and! a! transparent! cap! for! total reflection;

Figure! 2! shows! another! radial! medical! radiation delivery! device! that! can! be! freely! positioned inside! a! transparent,! inflatable! balloon! incorporating! temperature! sensing! fibers! as! well,! placed to! irradiate! the! prostate;

Figure! 3! is! a! detailed! view! of! Figure! 2! showing reflective! metal! coating! used! for! deflection;

Figure! 4! is! a! cross! section! of! Figure! 3;

Figure! 5! shows! a! conventional! state! of! the! art Photo! Dynamic! Therapy! Delivery! device;

Figure! 6! shows! a! delivery! device! with! spiral grooves;! and,

Figure 7! shows! a! power! control! system! operated! by! sensing! through! the! same! fiber.

DESCRIPTION! OF! THE! PREFERRED! EMBODIMENTS

It! is! an! object! of! this! invention! to! provide! a! new and! improved! radial-laser! delivery! device! to! overcome! the! disadvantages! of! prior! radial! laser! delivery! devices,! such! as! power! handling! capability, area! of! coverage,! extent! of! coverage,! radially! directedness! of! radiation! from! an! extended! source,! etc. By! "radial"! and! "radially"! are! meant! extending outwardly! from! the! central! axis! of! a! fiber! and! not parallel! thereto.! In! this! application,! they! are! meant to! include! extending! outwardly! at! right! angles! as well! as! at! any! other! angles! and! to! include! full circumference! and! only! partial! circumference! radiation.

Another! object! of! this! invention! is! to! describe! a control! mechanism! and! an! improved! device! method! to! carry! out! treatments! such! as! laser! prostatectomy! and! photodynamic! therapy.

Figure! 1! illustrates! a! side! view! of! present! invention! device! 100,! a! typical! preferred! embodiment of! the! invention,! at! its! distal! end.! The! optical! fiber! 1 has! a! core! 2,! a! cladding! 3! and! one! or! more protective! coating! layers! 4.! Core! 2! is! grooved! on one! side,! and! grooves! 5,! 6! and! 7! are! of! increasing size! and/or! angles,! as! shown.! Core! 2! distal! end! 8! is encapsulated! with! a! protective,! transparent! cap! 15 over! a! predetermined! length! so! as! to! cover! all! the grooves! 5,! 6! and! 7;! this! resulting! in! a! series! of! air pockets! 9,! 10,! 11! and! 12.! The! cap! can! be! affixed to! the! fiber! by! any! medically! safe! glue! 16.! If! the inclination! of! the! fronts! of! the! grooves! (facing! incoming! radiation)! measured! from! the! most! inclined ray! 17,! 18! and! 19! travelling! in! the! fiber! 1! is! chosen such! that! it! is! lower! than! the! angle! of! the! total reflection! limit! between! the! optical! fiber! core! and air, all! rays! coming! through! the! fiber! from! the proximal! end! (input! end! of! the! radiation! source,! or laser)! will! be! totally! reflected! and! thus! exit! in! radial direction! as! shown! by! the! typical! arrows! such! as arrow! 21.

By! progressively! increasing! the! depth! of! each groove! towards! the! distal! end! 8! of! the! fiber! 1,! more and! more! radiation! is! diverted! from! the! axial! path into! the! radial! direction! resulting! in! the! desired extended! directed! radiation.! This! creates! a! defined, predetermined! area! of! radiation! application! that! is much! greater! than! a! reflected! point! source.

Figure! 2! now! illustrates! how! another! such! device! 102! is! employed! to! shrink! the! prostate! gland and! thus! provide! a! free! passage! in! the! urethra.! As known,! the! prostate! gland! can! swell! and! thus! result in! an! inconvenience! for! a! high! number! of! men, particularly! at! higher! age,! in! as! much! as! the! ure-

thra! is! thus! partially! blocked! and! the! free! flow! of urine! can! be! obstructed.! It! is! known! that! by! irradiating! the! prostate,! and! thus! degenerating! and! shrinking! it! this! inconvenience! can! be! removed,! and! a free! passage! restored.! In! order! to! perform! this procedure! in! a! controlled! and! safe! manner! a present! invention! radial! medical! delivery! device 102! comprising! an! optical! fiber! 31,! a! multilumen channel! 32,! an! inflatable! balloon! 33! as! well! as temperature! sensing! fibers,! such! as! fibers! 34! and 35,! is! introduced! into! the! urethra! 35.! Fiber! 31! has grooves! 41,! 42! and! 43! and! cut! end! 44, as! shown. After! inflating! the! balloon! that! is! transparent! to! the radiation! wavelength! used! in! the! procedure! (example,! 1064! nm)! radiation! is! directed! at! the! prostate 36.! The! inclinations! of! the! grooves! 41,! 42! and! 43 and! cut! tip! 44,! vary! in! this! example,! so! that! the radiation! represented! incoming! by! arrows! 45,! 46, 47! and! 48,! and! outgoing! by! arrows! 51,! 52,! 53! and 54,! converges! toward! the! prostate! 36.

The! radiation! is! thus! effectively! penetrating! the urethra! wall! 38! in! a! less! concentrated! form! than! it is! hitting! the! prostate,! thus! limiting! the! damage done! to! it.

The! balloon! 33! can! be! cooled! by! gas! or! liquid to! further! protect! the! prostate! wall.! By! feeding! the temperature! reading! obtained! via! sensing! fibers! 34 and! 35! back! to! a! laser! power! control,! an! optimum radiation! level! can! be! obtained.

In! this! example! of! a! preferred! embodiment! of the! radial! medical! delivery! device,! the! grooves! 41, 42, 43! and! the! cut! tip! 44! of! the! distal! end! 50! of! the fiber,! shown! in! part! in! Figure! 3! are! at! least! partially covered! by! a! reflective! metal! 57,! 58! and! 59! (such as! gold)! to! deflect! the! radiation.! Dark! areas! 61,! 62 and! 63,! for! example,! receive! substantially! no! radiation.

Figure! 4! shows! a! cross! section! and! illustrates how,! by! flattening! the! lower! side! 60! of! the! fiber! 31 focusing! in! all! but! the! desired! dimension! and! direction! may! be! avoided.

The! superiority! over! the! present! state! of! the! art will! now! be! clear.! Compared! to! a! single! reflective (or! totally! reflective)! point! source! on! the! end! of! a fiber! the! energy! density! penetrating! through! the balloon! and! the! urethra! wall! is! much! lower! and! a certain! degree! of! focusing! can! be! achieved,! if desired,! towards! the! the! present! invention! for! prostate! degeneration,! a! fiber! of! synthetic! silica! could be! used! to! deliver! the! laser! power! at! 1064! nm.! The fiber! for! sensing! the! tissue! temperature! may! be! of silver! halide! semi-crystalline! material! (transmitting a! wavelength! range! between! 4! um! and! 16um).

Any! other! available! or! known! materials! may! be used! for! the! fiber! for! a! particular! application! without exceeding! the! scope! of! the! present! invention.! For example,! it! can! be! equally! possible! to! make! the radial! medical! radiation! delivery! device! employing

a silver halide fiber for the laser delivery itself.

In this case, a CO or CO₂ laser can be used as a radiation source with wavelength of around 5 μ m and typically 10.6 μ m. In this case, the same fiber through which the laser radiation passes for irradiating the tissue can also be used to measure tissue temperature as well, as illustrated in Figure 6 and Figure 7.

Figure 6 shows present invention device 106 a silver halide fiber consisting of core 91 and clad 92. In this case, circular cut angled grooves 93 and 94 and tip 96, as well as a transparent cap 95 are included. While the laser radiation 116 is targeted towards the tissue 107, the temperature radiation from tissue 108 is picked up by the fiber and transmitted via a reflector 112 formed at tip 96, in the optical path of the transmission, and fed back as shown by arrow. As shown in Figure 7, this feedback is diverted via prism 114 towards a laser control module 122 thus controlling the power output of the laser 123 in line with procedural requirements.

It is evident that in some instances it may be preferable from a manufacturing standpoint to fuse a tip of a fiber containing the grooves on to another fiber, thus effectively in the end obtaining a device similar in operative characteristics to the ones described so far, and the present invention device may include a fiber formed of such joined sections without exceeding the scope of the present invention.

Clearly, in some instances it may be advantageous to build the delivery system of more than one delivery fiber processing the characteristic as described so far in this invention, for instance in order to provide higher flexibility of the device while still maintaining a certain total cross section, a fiber bundle may be used, without exceeding the scope of the present invention. Such bundles may have fibers with identical configurations but slightly staggered to enhance transmission, or may form components of a single desired configuration, depending upon the application(s) intended.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Claims

1. A medical delivery system capable of emitting radiation with wavelengths between 190 nm and 16 μ m in one or more essentially directed, predetermined patterns, which comprises:
at least one solid optical fiber, having a core and a cladding on said core and said

cladding having a refractive index smaller than the core, having an input end suitably configured to connect to an appropriate radiation source and having a distal end in the proximity of which two or more grooves are penetrating into the core, said grooves having at least partial reflector capability so as to deflect radiation thereto radially in one or more predetermined patterns.

2. A medical delivery system as claimed in claim 1, further characterized by a cap being placed over said at least one fiber at its distal end and over said two or more grooves, and by the enclosure of gas pockets in the grooves by means of said cap.
3. A radial delivery system as claimed in claim 2, further characterized by filling the grooves with a material having a significantly lower reflective index than the fiber core.
4. A medical radiation delivery system as claimed in claim 1, wherein the grooves have a reflective coating on at least one side.
5. A medical radiation delivery system as claimed in claim 1, wherein said at least one fiber is a quartz glass or synthetic silica fiber and the radiation transmitted is between 180 and 3000 nm.
6. A medical radiation delivery system as claimed in claim 1, wherein the fiber is a silver halide fiber and the radiation transmitted is between 4 μ m and 16 μ m. In this case the cladding on the core may be air.
7. A medical radiation delivery system as claimed in claim 1, wherein the grooves are only on one side of the device.
8. A medical radiation delivery system as claimed in claim 1, wherein the grooves have inclinations which vary in the device so as to give a radiation pattern converging at a predetermined distance from the fiber axis.
9. A medical radiation delivery system as claimed in claim 1, which further includes means for collecting through the fiber, the heat radiation from the irradiated surface, thereby controlling the energy level delivered.
10. A medical radiation delivery device system as claimed in claim 1, which further includes one or more temperature control sensors affixed on to an inflatable balloon transparent at least

over! its! cylindrical! portion! to! the! radiation wavelength! used! and! incorporating! the! radiation! delivery! fiber! in! the! inside! of! said! inflatable! balloon.

11. A! medical! radiation! delivery! device! system! as claimed! in! claim! 10,! wherein! said! fiber! is! located! within! said! inflatable! balloon! in! a! movable! manner.

12. A! medical! radiation! delivery! system! as! claimed in! claim! 1,! further! comprising! dosage! monitoring! fibers! affixed! to! an! inflatable! balloon! transparent! at! least! over! an! essential! part! of! its surface! to! the! radiation! wavelength! used.

13. A! method! of! performing! a! laser! prostatectomy procedure,! comprising:

(a) the! inserting! of! a! cystoscope! into! the urethra

(b) positioning! a! device! which! includes! at least! one! solid! optical! fiber,! having! a! core and! a! cladding! on! said! core! and! said! cladding! having! a! refractive! index! smaller! than the! core,! having! an! input! end! suitably! configured! to! connect! to! an! appropriate! radiation! source! and! having! a! distal! end! in! the proximity! of! which! two! or! more! grooves! are penetrating! into! the! core,! said! grooves! having! at! least! partial! reflector! capability! so! as to! deflect! radiation! thereto! radially! in! one! or more! predetermined! patterns;! and,

(c) irradiating! the! prostate! area! to! be! degenerated.

14. The! method! of! claim! 13! wherein! said! device! is further! characterized! by! a! cap! being! placed over! said! at! least! one! fiber! at! its! distal! end! and over! said! two! or! more! grooves,! and! by! the enclosure! of! gas! pockets! in! the! grooves! by means! of! said! cap.

15. The! method! of! claim! 14! wherein! said! device! is further! characterized! by! filling! the! grooves! with a! material! having! a! significantly! lower! reflective index! than! the! fiber! core.

16. A! method! of! performing! a! prostate! degeneration! procedure! comprising:

(a)! inserting! at! least! the! distal! end! of! a device! into! the! urethra,! which! includes! at least! one! solid! optical! fiber,! having! a! core and! a! cladding! on! said! core! and! said! cladding! having! a! refractive! index! smaller! than the! core,! having! an! input! end! suitably! configured! to! connect! to! an! appropriate! radiation! source! and! having! a! distal! end! in! the proximity! of! which! two! or! more! grooves! are

penetrating! into! the! core,! said! grooves! having! at! least! partial! reflector! capability! so! as to! deflect! radiation! thereto! radially! in! one! or more! predetermined! patterns,! and! which further! includes! one! or! more! temperature control! sensors! affixed! on! to! an! inflatable balloon! transparent! at! least! over! its! cylindrical! portion! to! the! radiation! wavelength used! and! incorporating! the! radiation! delivery! fiber! in! the! inside! of! said! inflatable! balloon;

(b) positioning! it! as! necessary;

(c) inflating! the! balloon;! and,

(d) irradiating! the! prostate! area! to! be! degenerated.

17. The! method! of! claim! 16,! wherein! said! fiber! is located! within! said! inflatable! balloon! in! a! movable! manner.

18. Method! of! performing! photodynamic! therapy, comprising:

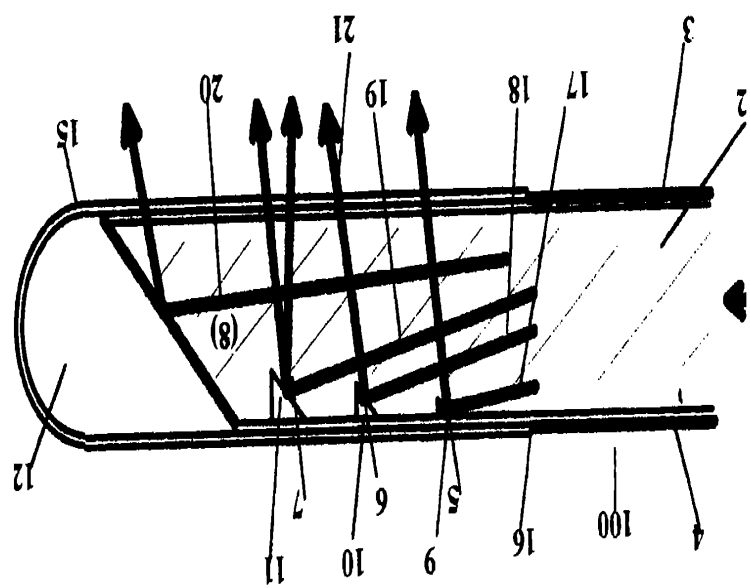
(a) applying! a! photosensitive! substance! to the! area! to! be! treated! or! to! the! distal! end! of the! device! set! forth! below;

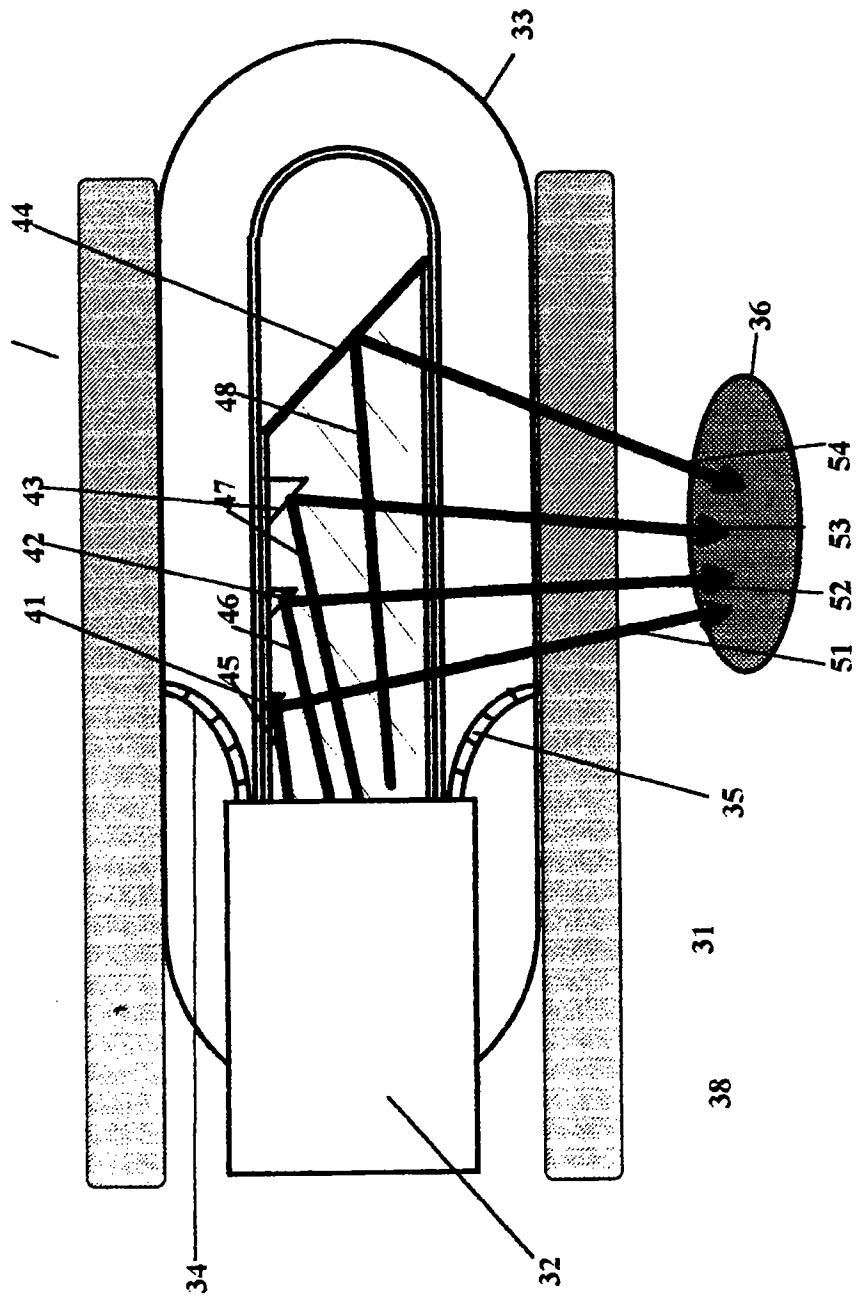
(b) inserting! a! device! which! includes! at! least one! solid! optical! fiber,! having! a! core! and! a cladding! on! said! core! and! said! cladding having! a! refractive! index! smaller! than! the core,! having! an! input! end! suitably! configured! to! connect! to! an! appropriate! radiation source! and! having! a! distal! end! in! the! proximity! of! which! two! or! more! grooves! are penetrating! into! the! core,! said! grooves! having! at! least! partial! reflector! capability! so! as to! deflect! radiation! thereto! radially! in! one! or more! predetermined! patterns;! and,

(c) irradiating! the! tissue! to! the! intended dosage! level.

19. The! method! of! claim! 18,! further! characterized by! a! cap! being! placed! over! said! at! least! one fiber! at! its! distal! end! and! over! said! two! or more! grooves,! and! by! the! enclosure! of! gas pockets! in! the! grooves! by! means! of! said! cap.

20. The! method! of! claim! 18,! further! characterized by! filling! the! grooves! with! a! material! having! a significantly! lower! reflective! index! than! the! fiber! core.





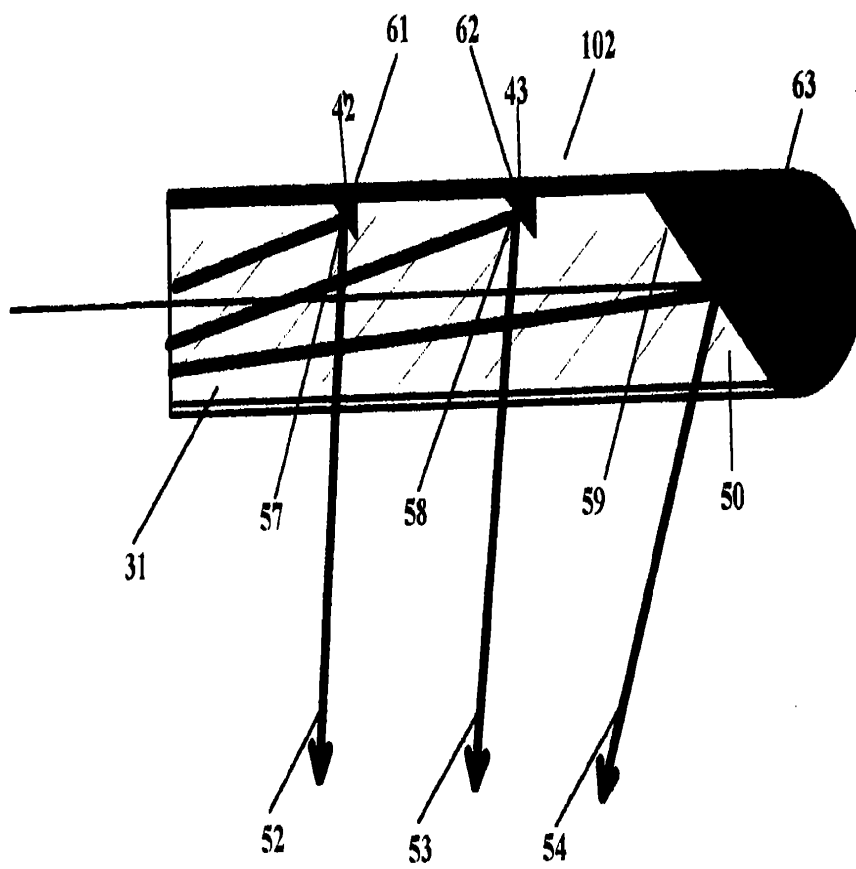


Fig 3

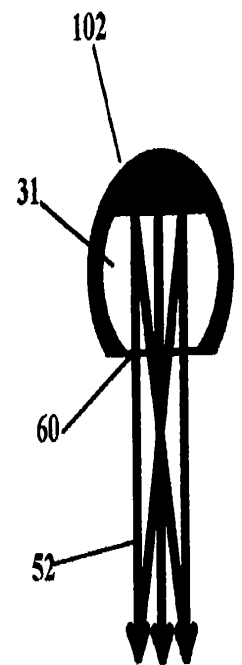


Fig 4

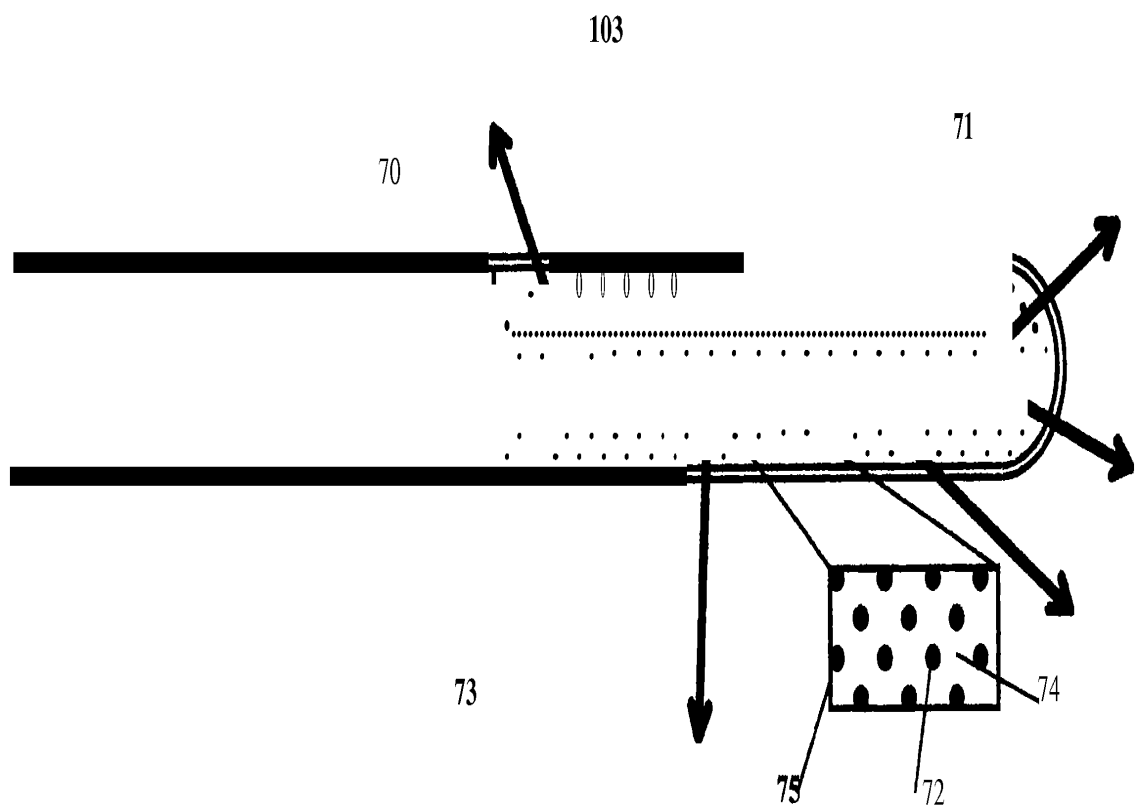
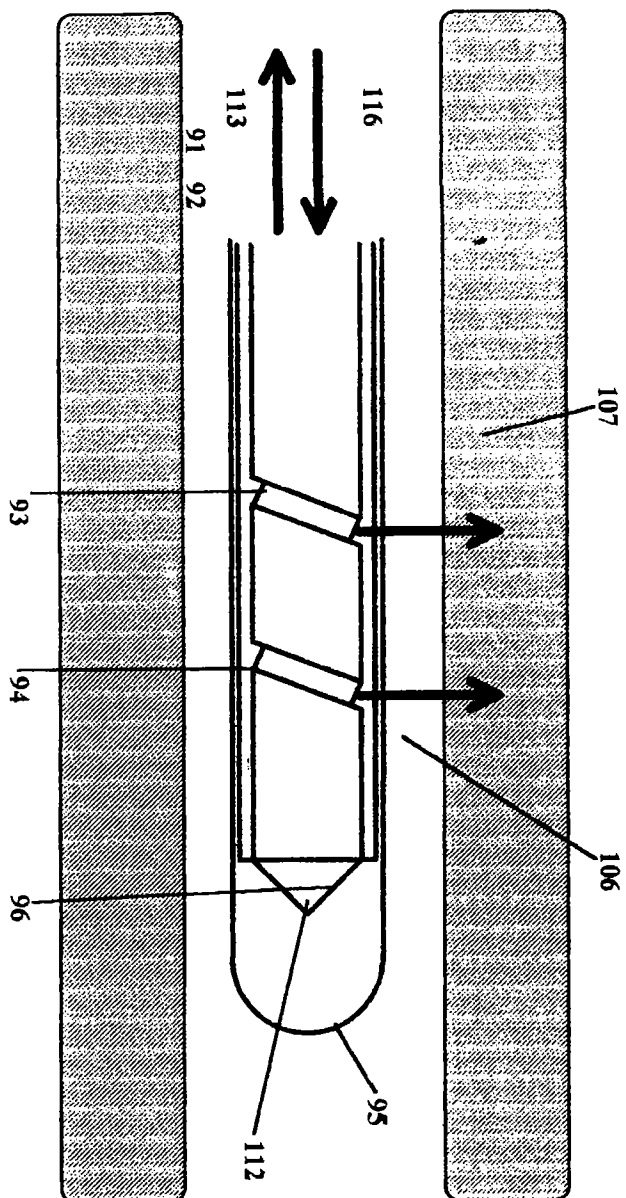
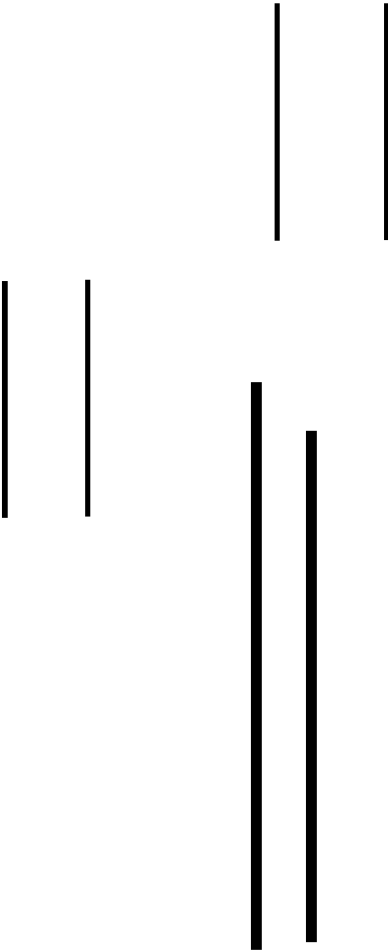


Fig 5







European Patent
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PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

EP! 93! 11! 0695

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
A	DE-A-39! 26! 353! (K! K! MORITA! SEISAKUSHO) *! column! 10,! paragraph! 3; figures 2C,12B,13H! *	1	A61B17/36 G02B6/28 G02B6/36
A	W0-A-90! 02349! (RAYNET) *! figures! 1,4,5,6! *	1	
A	W0-A-91! 06251! (SURGILASE) *! page! 5,! paragraph! 3! *	1	
A	EP-A-O! 292! 621! (SURGICAL LASER)		
A	US-A-4! 625! 724! (SUZUKI)		
A	EP-A-O! 182! 689! (MEDICAL LASER! R&D)		
A	EP-A-O! 073! 617! (PEMBERY)		
			TECHNICAL FIELDS SEARCHED (Int.Cl.5)
			A61B G02B

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see! sheet! C

Place of search

THE! HAGUE

Date of coayletloa Si the rears

11! February! 1994

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CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background.....
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document ated in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document



EP 93 11 0695 -C-

INCOiPLETE SEARCH

Claims searched completely : 1-12
Claims not searched : 13-20